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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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07/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/573,890	Applicant(s) NAKAMOTO ET AL.	
	Examiner Patricia L. Morris	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 10-15, 29-35 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16-28, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/29/06;7/6/06;3/27/08;9/22/08;5/6/09.

DETAILED ACTION

Claims 1-9, 16-28, 36 and 37 are under consideration in this application.

Claims 10-15, 29-35 and 38-40 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

Applicant's election with traverse of Group I and example A-53 in the reply filed on April 24, 2009 is acknowledged. The traversal is on the ground(s) that the restriction requirement is based on US practice. This is not found persuasive because for the reasons clearly set in the previous Office action. The compounds contain all variable cores which do not define a contribution over the prior art. Furthermore, note the numerous anticipatory references recited on the international search report and the claims were not searched completely since they are drawn to an extremely large number of possible compounds/composition/use.

The requirement is still deemed sound and proper and is therefore maintained.

This application has been examined to the extent readable on the elected compounds wherein A is 3-pyridinyl, X is $-C(=Y)-NH-(CH_2)_n-$, Y is oxygen or sulfur, E is 2-thienyl and n as set forth in claim 1, exclusively. All additional heterocycles and heterocyclic substituents pertain to non-elected subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-9, 16-28, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Fancelli et al. (US 6,414,013), Yoshikawa et al. (US 5,747,518) and Marfat et al. (US 6,630,218).

Fancelli et al. specifically recite the instant compounds wherein the pyridyl is substituted by chloro and the thienyl is substituted by phenyl and carbamoyl. Note compounds 105 and 106 in Table 3 therein.

Yoshikawa et al. disclose the instant compound wherein the pyridyl is substituted by chloro and the thienyl is substituted by phenyl. Note compound 1.97 therein.

Marfat et al. specifically recite the instant compounds wherein the thienyl is substituted by chloro or alkyl substituted by hydroxy and pyridyl is substituted by halo, nitro or cyano substituted phenoxy. Note example nos. 8, 61, 62, 68, 69, etc.

Hence, the instant compounds are deemed to be anticipated therefrom.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 16-28, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Fancelli et al., Yoshikawa et al. and Marfat et al.

Marfat et al. generically embrace the instant compounds. Note the compounds of formula (I) wherein R^1 is a thiophene and the specific reference example nos. 8, 61, 62, 68, 69, etc., therein. As discussed supra, Fanceilli et al. and Yoshikawa et al. recite specific compounds that are disclosed herein. Further, the prior art compounds differ from the compounds claimed herein as halogen analogs, a positional isomers and alkyl homologs. For example, the instant compounds wherein the pyridyl is substituted by fluorine or iodine would be a halogen analog of the compounds of Fancelli et al. or Yoshikawa et al. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at other compounds within the claimed genus. The motivation to make these compounds is their close structural similarities to the disclosed compound. While homology is considered to be present even if true "homology" is not present, such does not defeat the prima facie case of obviousness raised by the art. Attention, in this regard is directed to *In re Druey et al.*, 50 CCPA 1538, 319 F.2d 237, 138 USPQ 39, wherein Judge Worley, delivering the Court's opinion, stated:

that in "We need not decide here whether the compounds in question are properly labeled homologues. It appears to us from the authorities cited by the solicitor and appellants the term homologue is used by chemists at times in a broad sense, and at other times a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound." 50 CCPA 1541.

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Also, as the Court stated in *In re Payne et al.*, 606 F.2d 302, 203 USPQ 245 at 255

(CCPA 1979):

“the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound.”

In addition, any question of why would one conceive and use the similar compounds (i.e. “motivation”) is answered by the Court in *In re Gyurik et al.*, 596 F.2d 1012, 201 USPQ 552 at 557.

“In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties.”

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-9, 16-28, 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is a lack of description as to how the hydrates are produced and what hydrates are produced in the specification. Vippagunata et al. (Advanced Drug Delivery Reviews 48 (2001) 3-26) recites on page 18 that predicting the formation of hydrates of a compound and the number of molecules of water incorporated into the crystal lattice of a compound is complex and

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difficult. Guillory (in Brittain et al., NY:Marcel Dekker, 1999, pages 183-226, teach that hydrates can be prepared by recrystallization. Note page 203 therein. However, not all compounds will form hydrates. Note section 3.4 of Vippagunta et al.

Claims 1, 3-9, 16-28, 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparing the instant compound and its salts, does not reasonably provide enablement for preparing any and all unknown hydrates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification fails to prepare any hydrates or identify the hydrates obtained.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention

The nature of the invention is the preparation of a compound, its salts and hydrates.

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State of the Prior Art

Predicting the formation of hydrates of a compound and the number of molecules of water molecules incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of hydrates and hence generalizations cannot be made for a series of compounds. Note section 3.4 of Vippaguanta et al.

The amount of direction or guidance and the presence or absence of working examples

The working examples in the specification fail to show how any hydrates are produced. Further, Guillory on page 199 recites that compounds originally crystallized as hydrates can lose the water induced by heat or vacuum vaporization.

The breadth of the claims

The breadth of the claims is drawn to the preparation of the compound, its salts and all hydrate forms.

The quantity of experimentation needed

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the process of preparing all unknown hydrates.

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, 16-28, 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term hydrate in claims 1, 3-9, 16-28, 36 and 37 is indefinite to its meaning because it is unclear what is intended by applicants.

The expressions “comprising” and “may contain” in claims 1, 3 and 37 are open-ended and allows for inclusion of other active ingredients not contemplated by applicants.

Claim 36 is an improper composition claim because it fails to recite the presence of an inert carrier.

Claims 3 and 37 appear to be substantial duplicates. Claim 37 is drawn to compounds since the expression “antifungal agent” does not clearly define what applicants intend. If claim 37 is intended to be a composition claim, then it would be a substantial duplication of claim 36.

The claims measure the invention. *United Carbon Co. V. Binney & Smith Co.*, 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The C.C.P.A. in 1978 held “that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim”: *In re Priest*, 199 USPQ 11, at 15.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 16-28, 36 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11/658,903. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds wherein n is 1 are disclosed therein. The claimed compounds wherein n is zero or two are homologs of those recited therein. It has long been established that this type of structural relationship-varying the size of a linking carbon chain – is per se obvious. Specifically, *In re Shetty*, 195 USPQ 753, *In re Wilder*, 195 USPQ 426 and *Ex parte Gresham*, 121 USPA 422 all feature a compound with a C₂ link rejected over a compound with a C₁ link. Similarly, *In re Chupp*, 2 USPQ 2nd 1437 and *In re Coes*, 81 USPQ 369 have a C₁ link unpatentably over a C₂ link. Hence, patentable distinction is not seen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688.

The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/
Primary Examiner, Art Unit 1625

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July 20, 2009

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